Significant Analysis
Sections -011, -072, -202, -203, -204, -205, 206, -207, -208, -209 of chapter 246-100 Washington Administrative Code (WAC) and sections -505 and -520 of chapter 246-101 WAC

Briefly describe the proposed rule.

These proposed changes pertain to the following major areas:

- Editing and reorganization of rules for the purposes of simplicity and clarity;
- Notification of partners at risk of HIV infection;
- HIV information and pre- and post-test counseling
- HIV testing and consent for testing
- Information for persons with incurable sexually transmitted diseases.

Editing And Reorganization Of Rules For The Purposes Of Simplicity And Clarity;
WAC 246-100-206 includes some definitions and addresses a number of topics. In the proposed revision, the section has been divided into new sections (-202 through -205), edited to make clearer references, and some definitions moved to WAC 246-100-011, the definition section for chapter 246-100 WAC.

Notification Of Partners At Risk Of HIV Infection;
Rules regarding notification of partners at risk of HIV infection are addressed in WAC 246-100-072, WAC 246-101-505, and WAC 246-101-520.

The rule changes establish the local health officer as the primary responsible party for offering and providing partner notification services to newly reported HIV or AIDS cases, unless the principal health care provider recommends otherwise. In this case, the principal health care provider becomes the primary responsible party for offering and providing these partner notification services. The local health officer must initiate contact with the principal health care provider within 7 days of receiving a newly reported HIV or AIDS case for the purpose of providing partner notification services.

If the local health officer conducts the partner notification, the principal health care provider will inform the patient that the health officer will be contacting him or her in order to provide partner notification assistance.

Assistance with notifying partners, regardless of provider, must be conducted in a manner consistent with the most recent guidelines published by the Centers for Disease Control and Prevention.

The health officer may use the information related to the HIV-infected patient and the partner identifying information gathered for the purpose of partner notification to conduct an investigation under RCW 70.24.022 or 70.24.024, or as specified in WAC 246-101-520 and this

information, while being used in an active investigation under RCW 70.24.022 or 70.24.024, does not need to be destroyed.

HIV Information And Pre-/Post-Test Counseling

Rule changes regarding HIV information and counseling are contained in WAC 246-100-207, WAC 246-100-208, and WAC 246-100-209.

The proposed changes to these rules establish, simplify, and clarify the information-giving responsibilities of the provider ordering or prescribing an HIV test. Information about specific topics must be provided to all persons unless the person has been previously tested for HIV and declines the information. The specific information that must be provided includes the benefits and risks of HIV testing; how HIV is transmitted; meaning and importance of results; availability of anonymous testing; the need to notify partners if the test is positive; and HIV reporting requirements.

The provider must recommend and offer or refer any person at increased risk for HIV, or any person requesting it, to pre-test counseling. Patient refusal of pre-test counseling should not prevent the patient from receiving an HIV test.

Risk determination and pre- and post test counseling should be based on *The Revised Guidelines for HIV Counseling, Testing, and Referral, November 9, 2001* as published by the Centers for Disease Control and Prevention. Counseling should be client centered. At least one individual post-test counseling session is offered to all clients at the time of the results and provided or assured for all clients who test positive.

HIV Testing And Consent For Testing

Rule changes regarding HIV information and counseling are contained in WAC 246-100-207, WAC 246-100-208, and WAC 246-100-209.

Informed consent must be obtained or assured before the test is ordered or prescribed. The informed consent must be specific to HIV testing but not separate. Rules are clarified to permit either be verbal or written consent. Either way, the proposal requires documentation of patient consent.

The proposed rule changes remove reference to specific HIV tests or sequence of tests and allow for the use of new tests and testing methodologies as approved by the United States Food and Drug Administration (FDA), or the Centers for Disease Control and Prevention (CDC).

A new rule defines the responsibilities of the person informing a patient of unconfirmed reactive rapid HIV results. These results may be given to a client only if interpreted as preliminarily positive and if given with the information that further testing is required to confirm the test.

Proposed changes add the requirement that principal health care providers also offer and encourage HIV testing for patients seeking treatment for a sexually transmitted disease, consistent with the CDC's recommendations that HIV testing should be routinely offered as part

of medical care. In addition, the proposed changes require that individuals defined as at risk in CDC guidelines are offered or referred for HIV testing.

Information For Persons With Incurable Sexually Transmitted Diseases.
Rule changes regarding information for persons with incurable sexually transmitted diseases are contained in WAC 246-100-202. The proposal requires health care providers treating an infectious sexually transmitted to provide instruction as appropriate to the patient.

Is a Significant Analysis required for this rule?

Yes, a significant analysis is required for certain sections or subsections of the proposed revisions to these rules.

The following sections subsections of chapter 246-100 WAC require a significant analysis:
-072, subsections (1), (2), (3) and (5);
-202, subsection (1);
-207, subsections (1), (7) and (8)
-208, subsections (3) and (5); and
-209

The following sections subsections of chapter 246-101 WAC require a significant analysis:
-505, subsection (6); and
-520, subsection (1)

Department of Health has determined that no significant analysis is required for the rest of the proposed rule changes as they do not adopt substantive provisions of law pursuant to delegated legislative authority, the violation of which subjects a violator of such rule to a penalty or sanction; establish, alter, or revoke any qualification or standard for the issuance, suspension, or revocation of a license or permit; or adopt a new, or make significant amendments to, a policy or regulatory program, and therefore do not qualify as a significant legislative rule change.

A. Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

The general goal of chapter 70.24 of the Revised Code of Washington is to control and treat sexually transmitted diseases (STDs).

According to the legislative intent statement, specific objectives are to ensure programs are:

- Sufficiently flexible to meet emerging needs;
- Deal efficiently and effectively with reducing the incidence of sexually transmitted diseases; and
- Provide patients with a secure knowledge that information they provide will remain private and confidential.

To help meet these objectives, the State Board of Health is given broad responsibility to authorize and provide standards for the interview of persons with STDs and the investigation of exposed partners (RCW 70.24.022) and to adopt rules establishing minimum standards for pretest counseling, HIV testing, posttest counseling, and AIDS counseling (RCW 70.24.380). This is the first comprehensive review and update of rules related to these topics since their adoption in 1988/1989.

B. Determine that the rule is needed to achieve these goals and objectives, and analyze alternatives to rulemaking and the consequences of not adopting the rule.

Yes. These proposed rule changes are necessary.

As noted in the findings of the authorizing statute (RCW 70.24.015), the legislature recognized that medical knowledge and information about sexually transmitted diseases changes. A body of medical and behavioral research has emerged demonstrating the individual and public health benefits of early treatment of HIV infection with antiretroviral medications, the impact of knowledge of HIV serostatus on reducing the risk of further transmission of HIV, and the effectiveness of certain counseling approaches, which are not currently reflected in rule.

Further, from 2001 to 2003, the Department received three reports making recommendations or identifying barriers to HIV counseling and testing, and ensuring partners are notified of the exposure. These reports are:

- 2001 Washington State HIV Policy Summit Report
- Washington State HIV Prevention Study Committee Report (March 2002)
- March 2003 Issue Papers prepared by the Washington State Association of Local Public Health Officials and AIDSNETs

Also in 2003, the Centers for Disease Control and Prevention announced their *Advancing HIV Prevention Initiative*. The CDC initiative promotes removal of real and perceived barriers to routine testing, including "de-coupling" HIV tests in the medical setting from extensive, pre-test prevention counseling; encourages the use of rapid HIV testing; and efforts to assure partner notification.

Alternatives to rulemaking were not identified, as the identified barriers are with the existing rules. Therefore, to meet the goals and objectives of chapter 70.24 RCW, specifically having sufficient flexibility to meet emerging needs and dealing efficiently and effectively with reducing the incidence of sexually transmitted diseases it was determined that rule changes were necessary.

The consequence of not adopting the proposed rule changes are fewer persons will have the opportunity to learn they are infected with HIV, receive medical treatment, and change behaviors to reduce their risk of further transmission of the disease.

C. Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

These proposed rule changes are designed to protect public health by reducing HIV transmission through assuring effective HIV counseling and testing and partner notification referral services. The proposed rule changes also more clearly respond to the objectives of chapter 70.24 RCW, specifically by providing sufficient flexibility to meet emerging needs and dealing efficiently and effectively with reducing the incidence of sexually transmitted diseases.

The community costs of new HIV infections are high. The average lifetime cost of HIV care is estimated at $195,188 (1996 dollars)[1]. Reduction of HIV transmission within Washington State has significant individual and community benefits. Identification of HIV-infected persons early in the course of their infection can result in timely evaluation and antiretroviral treatment. Such "early treatment" has been linked to improved prognosis for the infected individual.[2] Individuals receiving antiretroviral therapy have been shown to be up to 50% less likely to transmit HIV infection to others.[3] This is a significant benefit to the health of the community.

The proposed rule revisions reduce identified barriers to the receipt of HIV testing and provide mechanisms for ensuring more effective notification of exposed partners. The proposal:

- Streamlines requirements to provide specific information and improves flexibility is to both the health care provider and the patient in meeting the patient's needs.
- Eliminates incorrect information from the rules that may facilitate HIV transmission
- Clarifies and makes consent requirements less burdensome.
- Allows providers to offer or encourage HIV testing for persons at risk.
- Requires providers to remind persons with infectious sexually transmitted diseases of the obligation to refrain from acts that may transmit the infection.

Taken as a whole, these rule changes result in more at risk persons will receiving HIV testing – an added cost. This cost is more than off-set for both the private and public health care systems by the significantly reduced costs associated with HIV information-giving; and unnecessary, unwanted, and ineffective counseling requirements. As noted earlier, the early identification of persons with HIV disease and notification of their exposed partners will have significant benefits to the health of the individual and of the community in addition to economic benefits. Presented below are HIV-related diagnostic related groups (DRGs) and their associated charges for Calendar Year 2002 from the Department of Health Hospital Discharge Data.

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[1] Cohen D, Wu S, Farley T. Comparing the Cost-Effectiveness of HIV Prevention Interventions. Journal Acquired Deficiency Syndrome, November 2004; 37:1404

[2] Mellors J, Rinaldo CR, Gupta P, et al. Prognosis in HIV-1 infection predicted by quantity of virus in plasma. Science 1996;272:1167-79.

[3] Musicco M, Lazzarin A, Nicolosi A, et al. Antiretroviral treatment of men infected with human immunodeficiency virus type 1 reduces the incidence of heterosexual transmission: Italian Study Group. Arch Intern Med 1994;154:1971-6.

HIV-Related DRG	No of Patients	Minimum Charge	Average Charges	Maximum Charges	Total Charges	Std. Div Charges
488	34	1,879	56,652	226,773	1,926,163	47,912
489	472	1,471	21,729	192,242	10,255,969	24,689
490	193	1,031	12,588	96,765	2,429,741	12,375
All	699		20,904		14,611,603	

The specific objectives and the specific directives to the State Board of Health are met with these proposed rule changes. The proposal adds flexibility to meet emerging needs and deals more efficiently and effectively with reducing the incidence of sexually transmitted diseases it was determined that rule changes were necessary. At the same time, the specific directives to the State Board of Health to provide standards for the interview of persons with STDs and the investigation of exposed partners (RCW 70.24.022) and to adopt rules establishing minimum standards for pretest counseling, HIV testing, post-test counseling, and AIDS counseling (RCW 70.24.380) are improved by reference to national guidelines and recommendations from the Centers for Disease Control and Prevention.

D. Determine, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

DOH staff worked closely with constituents and the public to minimize the burden of this rule and to establish language that would achieve the goals and objectives of the authorizing statute

DOH staff published alternative versions on the web (Draft #1 and Draft #2); conducted a series of publicized public forums across the state to gather public input; and, solicited additional comments through several venues including Email, mail, and telephone.

Public comment was gathered and considered on both drafts. Because of public input, elements of this draft were accepted while other elements were rejected and / or amended in further drafts. Summary comments for each of the major topic areas with the exception of editing and reorganization of rules for the purposes of simplicity and clarity follow:

Notification Of Partners At Risk Of HIV Infection;
Rules regarding notification of partners at risk of HIV infection are addressed in WAC 246-100-072, WAC 246-101-505, and WAC 246-101-520.

The final proposed rule change designates the local health officer as the primary responsible party to offer and provide partner notification services to newly reported HIV or AIDS cases, unless the principal health care provider recommends otherwise. In which case, the principal health care provider becomes the primary responsible party to offer and provide these partner notification services. The local health officer must initiate contact with the principal health care

provider within 7 days of receiving a newly reported HIV or AIDS case for the purpose of providing partner notification services.

An alternative considered was leaving the existing rule in place. This was rejected as the least likely to achieve the objective of the stature by dealing efficiently and effectively with reducing the incidence of sexually transmitted diseases. A second alternative of placing primary responsibility for partner notification on the private health care provider was considered. This alternative was rejected based on comments received from private health care providers regarding the burden that this rule would place on them.

The final proposed rule change requires that assistance with notifying partners, regardless of provider, shall be conducted in a manner consistent with the most recent guidelines published by the Centers for Disease Control and Prevention. An alternative considered would have applied solely to private health care providers. This alternative was rejected because of unequal treatment of public and private providers.

The final proposed rule change allows HIV-infected patient and partner identifying information gathered for the purpose of partner notification to be used for the purpose of conducting an investigation pursuant to RCW 70.24.022 or 70.24.024, or as specified in WAC 246-101-520 and such information, while being used in an active investigation pursuant to RCW 70.24.022 or 70.24.024, does not need to be destroyed. An alternative considered was to eliminate the requirement for record destruction. This was rejected when community-based agencies noted that this would conflict with similar requirements for destruction of HIV case reports.

HIV Information And Pre-/Post-Test Counseling

Rule changes regarding HIV information and counseling are contained in WAC 246-100-207, WAC 246-100-208, and WAC 246-100-209.

The proposed changes to these rules establish, simplify, and clarify the information-giving responsibilities of the person ordering or prescribing an HIV test for another. Information about specific topics must be provided to all persons unless the person has been previously tested for HIV and declines the information. The specific information that must be provided includes the benefits and risks of HIV testing; how HIV is transmitted; meaning and importance of results; availability of anonymous testing; the need to notify partners if the test is positive; and, HIV reporting requirements.

An alternative was considered to continue the specific requirement to always provide information to the patient about the option of anonymous testing. This alternative was rejected because in the private medical setting, offering a patient with signs or symptoms of HIV/AIDS an anonymous test is not likely to be in the best medical benefit of the patient.

HIV Testing and Consent for Testing
Rule changes regarding HIV information and counseling are contained in WAC 246-100-207, WAC 246-100-208, and WAC 246-100-209.

Informed consent must be obtained or assured before the test is ordered or prescribed. The informed consent must be specific to HIV testing but not separate. Rules are clarified to permit either be verbal or written consent. Either way, patient consent must be documented.

An alternative considered was to require all patients to give written, signed consent for HIV testing. This alternative was rejected because it would create an additional barrier to HIV testing.

Information For Persons With Incurable Sexually Transmitted Diseases.
Rule changes regarding information for persons with incurable sexually transmitted diseases are contained in WAC 246-100-202. The rule change requires health care providers treating an infectious sexually transmitted to provide instruction as appropriate to the patient regarding reducing the risk of disease transmission.

An alternative considered was requiring all health care providers to provide instruction to the patient regarding reducing the risk of disease transmission. This alternative was rejected as burdensome to health care providers not directly involved in the treatment of the infectious sexually transmitted disease.

E. Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.
The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

F. Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.
The rule does not impose more stringent performance requirements on private entities than on public entities.

G. Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.
The rule does not differ from any applicable federal regulation or statute.

H. Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.
There are no other applicable laws.